IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

VIRGIL SMITH, *individually,*
and ADAM SMITH, *through*
his legal guardian, Virgil Smith,

Plaintiffs,

v.

PHOENIX SEATING SYSTEMS, LLC,
d/b/a FALCON/LEBAC SYSTEMS, and
APRIA HEALTHCARE GROUP, INC.,

Defendants. **No. 09-cv-568-DRH-DGW**

MEMORANDUM AND ORDER

HERNDON, Chief Judge:

I. INTRODUCTION

Pending before the Court are the defendants' motions for summary judgment pursuant to FEDERAL RULE OF CIVIL PROCEDURE 56 (Docs. 113, 114). Defendant Phoenix Seating Systems, LLC (Phoenix), requests summary judgment as to plaintiffs' strict liability claims, Counts I and II (Doc. 114), while defendant Apria Healthcare Group, Inc. (Apria), requests summary judgment as to plaintiffs' negligence claims, Counts III and IV (Doc. 113). As plaintiffs have responded to defendants' requested relief (Doc. 122), these motions are ripe for judicial resolution. For the following reasons, the Court **DENIES** Phoenix's motion (Doc. 114) and **GRANTS** Apria's motion (Doc. 113).

II. BACKGROUND

The instant litigation arises from mental and physical injuries Adam Smith (Adam) and Virgil Smith (Virgil) incurred beginning on or before August 7, 2007, allegedly resulting from polyurethanes contained in Adam's custom-made wheelchair's armrests (*See* Doc. 54-1). Defendants' relationship to Adam's Gel Ovations Model 312G armrests (312G) forms the crux of the instant motions. Apria is a seller of medical equipment and devices, including the custom-made wheelchair at issue (*See* Doc. 113-2, pp. 31-32). Phoenix is a supplier of specialty wheelchairs and wheelchair components (Doc. 114-1, pp. 7-9). Phoenix advertises and distributes products it designs and manufactures, as well as products other entities design and manufacture (Doc. 122-3, p. 3). Specifically, it served as the original conceptual designer and marketer of the 312G (Doc. 113-7, p. 10).

Adam's custom-made wheelchair resulted from a consultation he had with an Apria seating specialist, Dennis Layton (Layton), in early 2007. Layton came to plaintiffs' home to perform an evaluation (Doc. 113-2, pp. 11-12). As a result of the evaluation, plaintiffs selected a variety of wheelchair components for Adam's wheelchair and discussed the 312G (Doc. 113-2, p. 35). Apria assembled the wheelchair and Layton delivered it to plaintiffs on March 30, 2007 (Doc. 114-7). At that time, the 312G armrests were not present (Doc. 113-2, pp. 49-50). On April 23, 2007, Layton met with plaintiffs and ordered the 312Gs for Adam's wheelchair, which plaintiffs received on June 21, 2007 (Doc. 113-2, p. 56; Doc.

114-9). Phoenix sold the 312Gs at issue to Apria (Doc. 54-1, p. 2; Doc. 122-3, p. 4).

Virgil testified at his deposition that the 312Gs arrived in a large box. Inside the box was a large, sealed plastic baggy containing the 312Gs. Virgil called Layton to discuss the 312Gs' installation. Virgil then opened the baggy and stated he was "engulfed" by an "overpowering" odor (Doc. 113-9, p. 41). He then placed the 312Gs in the garage to "air out" for approximately seven days, as he did not feel comfortable immediately placing them on Adam's wheelchair due to the odor. As the odor allegedly did not dissipate, Virgil placed them on the outdoor patio for approximately three to four days (Doc. 113-9, p. 43). At that point, as he felt the odor had sufficiently diminished, Virgil placed them on Adam's chair (Doc. 113-9, p. 44).

Adam had used the 312Gs for approximately seven to ten days when his nurse Lois Frailey (Frailey) noticed fluid-filled blisters forming on Adam's arms on August 7. 2007. Thus, Virgil, Melody Smith (Melody), Virgil's wife and Adam's mother, and Frailey took Adam to the emergency room where he received treatment (Doc. 113-9, p. 53).

Virgil testified that initial testing of the 312Gs indicated a heightened level of Mercury (Doc. 113-9, p. 70). Virgil also states that certain tests conducted at the direction of Dr. Rauckman, a toxicologist, indicated that the 312Gs' cover contained Cyanate (Doc. 113-9, p. 76).

Thus, plaintiffs filed the instant action in this Court on July 28, 2009, on the basis of diversity (Doc. 1). Plaintiffs' amended complaint alleges two counts of strict liability against Phoenix. Specifically, plaintiffs state that at the time the 312G left the possession and control of Phoenix it was, "in a defective and unreasonably dangerous condition" and that:

a. It contained polyurethanes which, when originally manufactured, sustained only partial polymerization of amines and isocynates, and an excess of the catalyst mercury;

b. The armrest was completely devoid of labeling;

c. The armrest contained no warnings of any kind, including a warning of the potential health risks posed by the materials used to manufacture the armrest.

(Doc. 54-1, pp. 3-4).

Plaintiffs' Counts III and IV allege claims of negligence against Apria. Plaintiffs state Apria,

a. Negligently and carelessly failed to inform plaintiff, the purchaser, that the product was improperly designed and/or manufactured in that the product contained polyurethanes which, when manufactured, sustained only partial polymerization of amines and isocynates, and an excess of the catalyst mercury;

b. Negligently and carelessly failed to inform the purchaser that the product was completely devoid of labeling;

c. Negligently and carelessly failed to inform the purchaser that the product contained no warnings of any kind, including no warning of potential health risks posed by the materials used to manufacture the armrest;

d. Negligently and carelessly failed to inform the purchaser that there were potential health risks posed by the materials used to manufacture the armrest.

(Doc. 54-1, p. 6).

Thus, as a result of these allegations, plaintiffs allege they have, "sustained prolonged exposure to a toxic chemical combination, suffering dermal lesions externally, as well as severe kidney, liver, and pulmonary damage." Additionally, plaintiffs allege, "permanent pain, mental anguish, disability and disfigurement," an accrual of large sums of medically-related expenses, permanent prevention from attending to their usual affairs and duties, and seek lost wages and income (*See* Doc. 54-1).

On June 2, 2010, Phoenix filed a third party complaint for contribution and indemnity against Taiwanese corporation, Velo Enterprise Co., Ltd. (Velo), as the manufacturer of the 312Gs, and Taiwanese corporation, Rattox Corporation (Rattox), as supplier (*See* Doc. 54). Velo answered the third party complaint on August 18, 2010, admitting, "it was a manufacturer of [the 312G]," and that, "it sold [312Gs] to [Rattox]" (Doc. 64, pp. 3, 4). Rattox admitted that it purchased 312Gs from Velo and sold them to Phoenix (Doc. 64, pp. 5, 6). Thereafter, Phoenix requested an admission from Velo that it, "manufactures [312Gs] using a proprietary gel bend." Velo objected to this request as vague (Doc. 114-5, p. 2). Velo admitted that Phoenix, "does not control the proprietary gel blend used by [Velo in its] manufacture of [312Gs]" (Doc. 114-5, p. 3).

As both defendants Phoenix and Apria seek an Order of this Court finding they are not liable for plaintiffs' injuries as a matter of law, they filed separate motions for summary judgment on February 22, 2012 (Docs. 113, 114). Phoenix

seeks summary judgment as to Counts I and II, plaintiffs' strict liability claims, as it argues it did not manufacture the 312G and had no knowledge or control over the proprietary gel used, and it had no duty to warn plaintiffs or label the 312G (Docs. 114, 115). Apria seeks summary judgment on Counts III and IV, plaintiffs' negligence claims against it.[1] Apria argues it is entitled to summary judgment pursuant to 735 ILCS 5/2-621, known as the "seller's exception" to products liability. Further, Apria states it had no duty to warn plaintiffs about the alleged risks of the 312G (Doc. 113). Plaintiffs naturally oppose defendants' legal assertions (Doc. 122).

III. LEGAL STANDARD

Summary judgment is proper where the movant shows "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(A); *accord Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). A genuine issue of triable fact exists only if, "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Pugh v. City of Attica, Ind.*, 259 F.3d 619, 625 (7th Cir. 2001) (quoting *Anderson Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

The movant bears the burden of establishing the absence of fact issues and entitlement to judgment as a matter of law. *Santaella v. Metro. Life Ins. Co.*, 123 F.3d 456, 461 (7th Cir. 1997) (citing *Celotex*, 477 U.S. at 323). Once the moving party has set forth the basis for summary judgment, the burden then shifts to the

[1] The Court notes that although Apria repeatedly references strict liability claims brought against it, plaintiffs only bring negligence claims against Apria (Doc. 54-1).

nonmoving party who must go beyond mere allegations and offer specific facts showing that there is a genuine issue for trial. FED. R. CIV. P. 56(e); *see Celotex*, 477 U.S. at 323–24. The nonmoving party must offer more than "[c]onclusory allegations, unsupported by specific facts," to establish a genuine issue of material fact. *Payne v. Pauley*, 337 F.3d 767, 773 (7th Cir. 2003) (citing *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1990)).

A party will successfully oppose summary judgment only if it presents, "definite, competent evidence to rebut the motion." *EEOC v. Sears, Roebuck & Co.*, 233 F.3d 432, 437 (7th Cir. 2000). The Court considers the record in the light most favorable to the nonmoving party, and draws all reasonable inferences in the nonmovant's favor. *Lesch v. Crown Cork & Seal Co.*, 282 F.3d 467, 471 (7th Cir. 2002). However, the Court accepts the nonmoving party's version of any disputed fact only if supported by relevant, admissible evidence. *Bombard v. Fort Wayne Newspapers, Inc.*, 92 F.3d 560, 562 (7th Cir.1996).

IV. LAW AND APPLICATION

This case is before the Court pursuant to diversity jurisdiction. Thus, the substantive law of Illinois controls the instant dispute, as the parties do not raise a conflict of law issue. *See Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938); *Fednav Int'l Ltd. v. Cont'l Ins. Co.*, 624 F.3d 834, 838 (7th Cir. 2010).

1. Phoenix's Motion for Summary Judgment on Counts I and II: Strict Liability

Under Illinois law, it is well-settled that recovery in a strict product liability action requires a plaintiff plead and prove that, "the injury complained of resulted

from a condition of the product, that the condition was unreasonably dangerous, and that it existed at the time the product left the manufacturer's control." *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 335 (Ill. 2008) (citing *Sollami v. Eaton*, 772 N.E.2d 215, 219 (Ill. 2002)). A court may find a product is unreasonably dangerous based on proof of any one of the following three conditions of the product: a physical defect, a design defect, or a failure of the manufacturer to warn of the danger or to instruct on the proper use of the product. *Id.* In Illinois, "in a products liability action, all persons in the distributive chain are liable for injuries resulting from a defective product, including suppliers, distributors, wholesalers[,] and retailers." *Hammond v. North Am. Asbestos Corp.*, 454 N.E.2d 210, 216 (Ill. 1983).

The Illinois Supreme Court has adopted section 402A of the Restatement (Second) of Torts, observing that a product is "unreasonably dangerous" due to a defect in either manufacturing or design when it is, "'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.'" *Mikolajczyk*, 901 N.E.2d at 335-36 (quoting *Lamkin v. Towner*, 563 N.E.2d 449, 458 (Ill. 1990)); Restatement (Second) of Torts § 402A, Comment *i*, at 352 (1965).

In theory, a toxic reaction to a product resulting from the presence of a toxin or poison in the product might render it defective or unreasonably dangerous. *See Adelman-Tremblay v. Jewel Co., Inc.*, 859 F.2d 517, 522 (7th

Cir. 1988) (citing § 402A, Comment *h*) (defective condition may arise "from harmful ingredients, not characteristic of the product itself . . . [and] from foreign objects contained in the product")).

However, a consumer who suffers an allergic reaction to a product *without any identifiable defect* may not generally invoke strict liable to recover from a manufacturer or seller. *Id.* (emphasis added) (citing Annotation, *Products Liability: Strict Liability in Tort Where Injury Results From Allergenic (Side-Effect) Reaction to Product,* 53 A.L.R.3d 298, § 3 (1973) ("[A] product, faultlessly manufactured and containing no impurities, is not rendered defective per se, within meaning of the doctrine of strict liability in tort, by the mere fact that it causes injury to certain individuals who, because of hypersensitivity or other peculiarity of makeup, suffer an allergenic or idiosyncratic reaction when exposed thereto.")); *see also Presbrey v. Gillette Co.*, 435 N.E.2d 513, 519-20 (Ill. App. 1982) (Concerning allergic reactions to products, "[t]he unusual susceptibility of the consumer is generally recognized as a complete defense where the manufacturer did not know or had no reason to know that a very few users of his product might be injured," as, "[t]he proximate cause of injury is attributed to the idiosyncrasy or allergy of the plaintiff and not to a failure to warn of a defect in the product.").

Phoenix argues it is not liable as a matter of law for plaintiffs' strict liability claims, as it did not manufacture the 312G and had no knowledge or control over the proprietary gel used in the 312G's manufacture, it had no duty to warn of a

risk that is remotely possible to the unknown few in the population, and there is no duty to label wheelchair armrests.

a. Phoenix's Status as Manufacturer

Phoenix first argues that although it, "originally conceptualized the general design of a gel filled armrest, Phoenix did not participate in the manufacture of the 312G, nor did Phoenix have any control over or access to the polymerization process or the components used in the polymerization process" (Doc. 114-2, pp. 10, 45-46, 133-137). Further, Phoenix reiterates that it was not aware of the exact components used in Velo's proprietary gel blend (Doc. 114-2, p. 46). Accordingly, Phoenix argues it had no control over the polymerization process and no control over the components and chemicals used in that process.

Plaintiffs respond by citing the Federal Food, Drug, and Cosmetic Act's (FDCA) various definitions of manufacturer. *See* 21 C.F.R. §§ 806.2(g)(1),(2), 807.3(d)(2), 820.3(o). Plaintiffs state Phoenix would receive the 312Gs in large boxes from Rattox. To prepare the individual 312Gs for shipment to dealers such as Apria, Phoenix would place the individual 312Gs in plastic bags with screws for attachment, seal them, and then place them in another box for shipment (Doc. 122-1, pp. 26-31). Further, as the 312Gs were not labeled upon Phoenix's receipt, it would place a sticky label with the words 312G, the size of the arm rest, and possibly the name of Phoenix's website on the package before shipment (Doc. 122-1, p 36). Finally, plaintiffs note that Phoenix admits that it, "specif[ied] the use of a gel armpad, the size of the gel armpad and the location of drill holes on the

underside of the armpad in order to allow the armpad to be fastened to wheelchairs" (Doc. 122-3, pp. 2-3). Thus, as Phoenix repackaged the 312Gs and initiated their specifications, plaintiffs argue they "manufactured" the 312G under the FDCA's definition.

Without commenting on whether Phoenix satisfies the FDCA's definition of manufacturer, the Court notes confusion as to the relevance of Phoenix's status as a manufacturer. As explained above, all parties to the distribution chain are liable for injuries resulting from a defective product. Phoenix admits that it sold the 312Gs at issue to Apria, which then sold them to the ultimate users; plaintiffs. Thus, Phoenix's status as a supplier of the 312Gs, as opposed to a manufacturer, does not warrant judgment as a matter of law in its favor as to the strict liability counts against it.

b. "Unreasonably Dangerous"

Phoenix argues it has a complete defense to plaintiffs' strict liability claims against it, as plaintiffs' injuries resulted from their idiosyncrasies or allergies and not from Phoenix's failure to warn. Phoenix relies on *Presbrey* as the basis of its assertion. *Prespbrey,* 435 N.E.2d at 522. In *Presbrey,* the Illinois Appellate Court reversed a grant of judgment in plaintiff's favor for his severe reaction after using defendant's anti-perspirant. The plaintiff charged negligence in failure to sufficiently test the product, to warn of inherent dangers and to list and warn of dangerous contents. Additionally, he brought breach of express warranty and products liability counts. In reversing the trial court's judgment, the court found

the plaintiff's reaction "idiosyncratic," as he was unusually susceptible to injury caused by the use of the anti-perspirant. The court noted that a seller of a product is not liable to a consumer who suffers an allergic reaction, "*if the product contains no defect or ingredient which would cause harm to the 'average' person.*" *Id.* at 519 (emphasis added) (citing *Stanton v. Sears Roebuck & Co.*, 38 N.E.2d 801, 803 (Ill. App. 1942) (plaintiff bore burden of presenting evidence that dyes in dress contained any harmful or poisonous substance of any kind)). Thus, *Presbrey* reiterates that in the failure to warn context, "if the product does not threaten severe harm to the ordinary consumer, then it is reasonably fit for the purpose for which it is sold," as, "[t]he proximate cause of injury is attributed to the idiosyncrasy or allergy of the plaintiff and not to a failure to warn of a defect in the product." *Id.* at 520.

However, instantly, plaintiffs allege not only that Phoenix failed to warn of possible dangers associated with the 312Gs, but also that the 312Gs are defective. *Cf. Adelman-Tremblay*, 859 F.2d at 522 ("In the present case, although the plaintiff has not alleged any defect in the cyanoacrylate glue, she argues the defendants should be held strictly liable for failure to warn of the possibility of an adverse allergic reaction to the glue."); *see also Friedman v. Merck & Co.*, 131 Cal.Rptr.2d 885, 893 (Cal. App. 2003) (compiling cases) ("There is significant authority to the effect that there is no duty to warn of the possibility of rare, idiosyncratic hypersensitive, or unusual reaction to an otherwise safe and useful product.").

Plaintiffs allege the 312G, "was physically defective and unreasonably dangerous because it contained several toxic compounds, due- at least in part- to the polyurethanes being only partially polymerized while being mixed." Plaintiffs offer a report of Dr. Elmer Rauckman, a toxicologist, in support of this assertion (Doc. 122-4). Dr. Rauckman states that Chemir Analytical Laboratories conducted two sets of tests on the 312Gs. First, an analysis of the gel which filled the armrest. Second, an analysis of the surface material covering the gel. Dr. Rauckman states that the analysis of the surface material demonstrated, "the presence of Mercury, isopherone diisocynate, triehtylene diamine, and various other free amines." He goes on to state, "Mercury's toxicity is well established affecting multiple organs, isopherone dissocynate is among the most potent of sensitizers and the free amines are corrosive to the skin at high concentrations or in the pure state." Thus, in Dr. Rauckman's opinion, "the simultaneous exposure to these three agents was the cause of the kidney damage, dermal lesions, and respiratory tract symptoms experienced by [Virgil and Adam] and indirectly resulted in the hepatotoxicity (liver) experienced by Adam." Dr. Rauckman opines, "there was a problem with the formulation of the urethane batch employed in [the] manufacture of the polyurethanes used in this product, resulting in only a partial polymerization and an excess of catalyst and unreacted monomers" (Doc. 122-4, p. 2).

Phoenix offers the opinion of Dr. Michael E. Mullins who opines that the, "compounds found in the polyurethane foam armrests does not indicate or prove

an acute or sub-acute toxic exposure." He further opines, "the only health effect which can be attributed to the arm rests is the appearance of a skin rash on Adam's forearms" (Doc. 114-13, p. 2). Thus, Phoenix relies on Dr. Mullins' report, in addition to the existence of Adam's and Virgil's numerous medical conditions and ailments (Docs. 114-10, 114-13), as holding plaintiffs are "unusually susceptible" consumers to which Phoenix had no duty to warn. Further, Phoenix points to its lack of specific knowledge as to the exact chemical make-up of the 312G, as holding it had no duty to warn.

As explained above, plaintiffs do not merely allege Phoenix had a duty to warn, but also that the 312G was defectively designed and/or manufactured. It is clearly disputed between the parties whether the proximate cause of plaintiffs' alleged injuries was a defect in the manufacture and/or design of the 312G, or an unusual susceptibility of plaintiffs. In considering the record in the light most favorable to plaintiffs and drawing all reasonable inferences in their favor, the Court finds there are genuine disputes of material fact which preclude judgment as a matter of law in Phoenix's favor at this time. *Lesch,* 282 F.3d at 471.

c. FDCA Requirements

Finally, although Phoenix does not directly raise the issue and cites no case law in support of its position, Phoenix impliedly argues that plaintiffs' claims are preempted by the express preemption provision of the Medical Device Amendments (MDA) to the FDCA, 21 U.S.C. § 360c *et seq.*, which preempts products liability claims in the case of medical devices approved by the Food and

Drug Administration's (FDA's) pre-market approval (PMA) process. The MDA authorizes the FDA to regulate the safety and effectiveness of medical devices. The MDA's express preemption clause states,

> [N]o State or political subdivision may establish or continue in effect with respect to a device intended for human use any requirement-(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

> In 1996, the Supreme Court held that lawsuits brought under state law against medical device manufacturers who submit "premarket notification" to the Food and Drug Administration are not preempted by 21 U.S.C. § 360k(a) when liability is premised on theories that the device was defective and unreasonably dangerous and that the manufacturer failed to use reasonable case in the device's design, manufacture, assembly, and sale.

Hofts v. Howmedia Osteonics Corp., 597 F. Supp. 2d 830, 832 (S.D. Ind. 2009) (Hamilton, J.) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481, 494-95 (1996)). Additionally, in 2008, the Supreme Court held that lawsuits brought under state law against medical device manufacturers who obtain federal PMA are preempted by Section 360k(a) of the MDA when liability is premised on violations of state law requirements that are "in addition to or different from" federal requirements regulating devices. *Id.* (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)).

Thus, it is necessary to discuss the different between "notification" to the FDA and the PMA process. Under the MDA, there are three classes for medical devices depending on the risks associated with the device. Class I devices are those for which general controls, such as labeling requirements, "are sufficient to

provide reasonable assurance of [their] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(A)(i). They include such things as "elastic bandages and examination gloves" and are "subject to the lowest level of oversight." *Riegel,* 552 U.S. at 316. Class II devices are subject to heightened oversight mechanisms, such as "performance standards [and] postmarket surveillance," 21 U.S.C. § 360c(a)(1)(B). Class III devices are the highest class, as they present a potentially unreasonable risk of injuring patients or they are used to sustain life. *See* 21 U.S.C. § 360c(a)(1)(C). There are two ways for a Class III device to be approved for market: the Section 510(k) process or the PMA process. The Section 510(k) review process is not "specific to the device in question [representing] . . . entirely generic concerns about device regulation generally." *Riegel,* 522 U.S. at 322 (citing *Lohr,* 518 U.S. at 501). Thus, as no specific federal requirements are imposed on Class III medical devices approved under Section 501(k), state law claims against such devices are generally not preempted under the MDA.

However, as the PMA process is the most rigorous review process, applicable to only a small percentage of Class III medical devices, the MDA's preemption applies to state law claims that are different from, or in addition to, the federal requirements, as such medical devices undergo specific federal safety review. *See id.* at 323.

Instantly, the parties dispute whether the 312G is a "wheelchair accessory" under 21 C.F.R. § 890.3910 and thus "exempt from the current good manufacturing practice requirements of the quality system regulation in part

820," or as plaintiffs argue, a "wheelchair component" under 21 C.F.R. § 890.3920 and thus not exempt from the current good manufacturing practice requirements. Most importantly, the Court notes that regardless of the 312Gs label, both "wheelchair accessories" and "wheelchair components" are Class I devices. As explained above, Class I devices are subject only to general controls. *See* 21 U.S.C. § 360c(a)(1)(A). As such, Phoenix has not presented, nor has the Court independently found, a persuasive argument for finding the MDA preempts plaintiffs' claims. *See Nat'l. Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988, 997 (8th Cir. 1994) ("[T]he FDA would not preempt any and all tort actions against manufacturers of, say, crutches or tongue depressors simply by placing those items in class I."). Thus, on the basis of the limited record before the Court, the Court cannot hold that the MDA preempts plaintiffs' claims.

Finally, concerning whether the 312G is an "accessory" or a "component," the Court notes that Phoenix has repeatedly referred to the 312G as an "armrest" throughout its instant motion. 21 C.F.R. § 890.3920 specifically lists "[a]rmrests" as "wheelchair components." However, as Phoenix has not offered a persuasive reason for finding either 21 C.F.R. § 890.3910 or 21 C.F.R. § 890.3920 are exempt from the general labeling requirements of the MDA, the Court does not find it necessary to determine whether the 312G is a "component" or "accessory" at this time. Thus, for the above stated reasons, Phoenix's motion for summary judgment is **DENIED** (Doc. 114).

2. Apria's Motion for Summary Judgment on Counts III and IV: Negligence

Apria argues it is entitled to summary judgment on both negligence counts against it, as it has met the requirements of 735 ILCS 5/2-621, the "seller's exception" to product liability. Further, Apria alleges plaintiffs have not demonstrated it had a legal duty to warn plaintiffs.

a. 735 ILCS 5/2-621

Apria first alleges the negligence claims against it require dismissal under Illinois' "seller's exception" to product liability actions. *See* 735 ILCS 5/2-621. Surprisingly, Apria fails to mention that this Court has already held that Section 2-621 does not apply to the negligence claims against Apria (Doc. 39). To reiterate the reasoning for the Court's previous ruling, prior to 1995, Section 2-621 applied only to actions in strict liability; plaintiffs who brought actions against a non-manufacturer defendant under a negligence theory were not subject to dismissal under Section 2-621. *Link by Link v. Venture Stores, Inc.*, 677 N.E.2d 486, 989 (Ill. App. 1997). However, in 1995, Public Act 89-7 amended Section 2-621, to provide that it applied to "any theory or doctrine." Importantly, the Illinois Supreme Court in *Best v. Taylor Machine Works,* found "core provisions" of Public Act 89-7 unconstitutional and voided the entire act on the principle of inseverability. 689 N.E.2d 1057 (1997). Therefore, the version of Section 2-621 that was in effect prior to the 1995 amendment is currently applicable. *Murphy v. Mancari's Chrysler Plymouth, Inc.*, 887 N.E.2d 569, 572 n. 2 (Ill. App. 2008).

In arguing that the negligence claims against it require dismissal under Section 2-621, Apria erroneously relies on *Ungaro v. Rosalco, Inc.*, 948 F. Supp. 783, 784 (N.D. Ill. 1996) (Kocoras, J.), which held the "seller's exception" applied to strict liability and negligence actions. As *Ungaro* predated *Best* by a year, it applied the amended version of Section 2-621, which is no longer good law. The Court sincerely hopes Apria's reliance on such unreliable precedent demonstrates a lack of research, not its intent to deceive. Regardless, the Court reaffirms its previous ruling in finding that Section 2-621 does not apply to plaintiffs' negligence claims against Apria.

b. Negligent Failure to Warn

Although neither party addresses the general law applicable to the instant dispute, under Illinois law, a product liability action asserting a claim based on negligence falls within the framework of common law negligence. *See Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 263 (Ill. 2007) (citing *Flaugher v. Sears, Roebuck & Co.*, 378 N.E.2d 337 (1978)). Thus, a plaintiff must establish the existence of a duty of care owed by the defendant, a breach of that duty, an injury that was proximately caused by that breach, and damages. *Id.* (citing *Ward v. K mart Corp.*, 554 N.E.2d 223 (1990)). The key distinction between a negligence and strict liability claim is the concept of fault, as a defendant's fault, in addition to the condition of the product, is at issue in a negligence claim. *Id.* (citations omitted). Therefore, it is not enough to show the product is defective or not reasonably safe; the plaintiff must also show that the defendant knew, or in the

exercise of ordinary care should have known, of that unsafe condition. *Brobbery v. Enter. Leasing Co. of Chicago*, 935 N.E.2d 1084, 1093 (Ill. App. 2010); *see Gray v. Nat'l Restorations Sys., Inc.*, 820 N.E.2d 943, 956 (Ill. App. 2004) ("A duty to warn exists when there is unequal knowledge and the defendant, possessed with such knowledge, knows or should know that harm might occur if no warning is given.").

Relevantly, Section 388 of the Restatement (Second) of Torts delineates a duty to warn of known defects under negligence principles for suppliers of chattels providing:

> § 388 Chattel Known to Be Dangerous for Intended Use
>
> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
>
> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
>
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
>
> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388, at 300–01.

Instantly, Apria argues it did not have a duty to warn plaintiffs of the 312Gs' allegedly defective manufacture and/or design. First, similarly to Phoenix, Apria argues the 312gs are "wheelchair accessories" under 21 C.F.R. § 890.3910, not "wheelchair components" under 21 C.F.R. § 890.3920. Thus, Apria was not

required under the MDA to label the 312Gs. Plaintiffs' two-page response, which is completely devoid of relevant case law or specifically applicable statutory provisions on the subject, merely states, "Apria had a duty to label" under the FDCA. Again, without commenting as to whether the 312G is an "accessory" or "component," the Court notes that Apria has also failed to demonstrate that either Section 890.3910 or Section 890.3920 are exempt from the general labeling requirements of the MDA.

Regardless, assuming the general labeling requirements of the MDA apply to the 312G, plaintiffs have failed to demonstrate how such requirements are capable of imposing a common law duty to warn upon Apria, let alone a breach of said duty. Plaintiffs do not provide the Court with the MDA provisions which it argues demonstrate such duty and/or breach, nor has the Court's independent review sufficiently revealed said provisions. Thus, the Court cannot hold that the MDA provides evidence of Apria's alleged common law duty to warn.

Next, most relevant to the instant dispute, Apria argues it did know, nor have reason to know, of the alleged defect. Apria alleges it did not manufacture the 312G, take any part in its design, have knowledge concerning the specific materials contained in the 312G, or have knowledge of complaints similar to plaintiffs' instant grievances. In support, it offers Layton's deposition in which he testified Apria does not manufacture any of the wheelchair components it sells (*See* Doc. 113-2, p. 32). He further stated Apria did not have any knowledge concerning the 312Gs, "manufacturing ingredients or processes" (Doc. 113-2, p.

42). Instantly, Apria, or more specifically, Layton, did not even place the 312Gs on the subject wheelchair; Virgil did (Doc. 113-9, p. 44). Further, when asked, "[d]id you have any concern in your mind that there might be a problem with [the 312Gs]?" Layton stated, "I did not have any concern . . . to my knowledge, there have been no other reactions similar to Adam's" (Doc. 113-2, pp. 71-72). Additionally, Tami Morris (Morris), an Apria operations manager during the relevant time period who dealt with the instant dispute, testified she had no recollection of similar complaints (Doc. 113-3, pp. 65, 107). Morris further testified that had there been similar complaints, they would have been brought to her attention (Doc. 113-3, p. 99).

As to Apria's dealings with the 312Gs upon their arrival from Phoenix, Layton was asked, "[w]hat is your understanding as to what if anything Apria would have done relative to these armpads between the time that they were received from [Phoenix] and the time they were tendered to UPS for delivery?" Layton stated, "[t]he box would have been opened to ensure that the quantities were correct and the box would have been resealed and taken to the shipping department" (Doc. 113-2, pp. 77-78).

As plaintiffs' response does not address Apria's argument concerning its lack of knowledge, plaintiffs do not dispute such allegations. Moreover, plaintiffs' complaint does not allege Apria had any role in the 312gs' design or manufacture, or knowledge of the 312Gs' alleged defective design or manufacture (*See* Doc. 54-1). Similarly, plaintiffs have not instantly offered evidence demonstrating Apria

was involved in the 312Gs' manufacture or design, or that other complaints or reactions to the 312G have ever been reported. Thus, on the basis of the record before the Court, plaintiffs have failed to demonstrate Apria possessed superior knowledge and consequently had a duty to warn about the alleged dangers associated with the 312G. *See Gray*, 820 N.E.2d at 957.

Further, plaintiffs seem to argue Apria's offer to split the costs of testing with Phoenix demonstrates Apria undertook a duty to warn plaintiffs. However, to the extent plaintiffs' allege this voluntary undertaking gave rise to a duty to warn, this argument must fail. Apria agreed to split the cost of testing *after* the alleged injuries took place. Thus, their alleged breach in violation of this duty could not have caused the injuries in dispute. *See Vancura v. Katris*, 939 N.E.2d 328 (Ill. 2010) ("[p]ursuant to the voluntary undertaking theory of liability, one who gratuitously or for consideration renders services to another is subject to liability for bodily harm caused to the other by one's failure to exercise due care."). Accordingly, plaintiffs have not offered evidence sufficient to demonstrate genuine issues of material fact exist as to plaintiffs' Counts III and IV for negligence. Thus, Apria's motion for summary judgment is **GRANTED** (Doc. 113).[2]

[2] Apria further relies on the Fair Packaging and Label Act, which it argues holds it was not required to label the 312G. *See* 16 C.F.R. § 500.4. However, Apria also contends the 312G is a device covered under the FDCA. As 16 C.F.R. § 500.2 specifically exempts devices covered under the FDCA from the Fair Packaging and Label Act's regulations, the Court does not address Apria's argument that the Fair Packaging and Label Act holds it was not required to label or otherwise warn plaintiffs. *See* 16 C.F.R. § 500.2(c).

V. CONCLUSION

For the above-stated reasons, defendant Phoenix's motion for summary judgment is **DENIED** (Doc. 114). Defendant Apria's motion for summary judgment is **GRANTED** (Doc. 113). Accordingly, plaintiffs' Counts III and IV for negligence are dismissed with prejudice.

IT IS SO ORDERED.

Signed this 10th day of September, 2012.

Digitally signed by David R. Herndon
Date: 2012.09.10 15:51:41 -05'00'

Chief Judge
United States District Court